

Mail Stop Interference  
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Paper 62  
Entered: 24 February 2009

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Yeda Research and Development Co., Ltd.,  
Junior Party  
(Patent 7,108,999,  
Inventors: David Wallach, Mark Boldin,  
Eugene Varfolomeev and Igor Mett),

v.

The Regents of the University of Michigan,  
Senior Party  
(Application 08/443,982  
Inventors: Vishva M. Dixit and  
Karen O'Rourke).

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Patent Interference 105,545 (RES)  
(Technology Center 1699)

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*Before* SCHAFFER, LANE and MEDLEY, *Administrative Patent Judges.*  
SCHAFFER, *Administrative Patent Judge.*

Judgment - Merits - Bd.R. 127

1 Michigan filed an amendment narrowing and canceling some of its  
2 claims. Paper 60. The parties jointly moved that as to the parties' remaining

1 claimed subject matter, there is no interference-in-fact. Paper 45. That  
2 motion was granted. Paper 61. It is appropriate, therefore, to enter  
3 judgment. Accordingly, it is

4 ORDERED that the Office is authorized to issue a patent to Michigan  
5 including Claims 61, 72, and 76-78 (Paper 60);

6 FURTHER ORDERED that Michigan is not entitled to claims  
7 directed to the subject matter of the claims listed below (Schedule A) which  
8 were cancelled by Michigan's amendment:<sup>1</sup>

9 Schedule A

10 Claims 62-68

11 Claims 70-71

12 Claim 72 depending from claims 62-68 and 70-71

13 Claim 73 depending from claims 62-68 and 70-71

14 Claims 74-75

15 Claim 76 depending from claims 74 and 75

16 Claim 77 depending from claims 74 and 75

17 Claim 78 depending from claim 74.

18 FURTHER ORDERED that Michigan's claims listed in Schedule A  
19 are finally refused (35 U.S.C. § 135(a));

20 FURTHER ORDERED that a copy of this judgment be made of  
21 record in the files of Application 08/443,982, and Patent 7,108,999; and

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<sup>1</sup> See Application 08/443,982, Supplemental Amendment after Final Office Action received by the Office January 24, 2000, and authorized for entry by Examiner Romeo on February 2, 2000 and Paper 12 in this interference. The supplemental amendment includes the claims suggested for interference by the examiner and includes all of Michigan's claims involved in the interference. Paper 1, p. 3, ll. 28-30. Michigan's amendment (Paper 60) cancelled the claims listed in Schedule A.

- 1 FURTHER ORDERED that if there is any settlement agreement or  
2 related documents which have not been filed, attention is directed to  
3 35 U.S.C. § 135(c) and 37 C.F.R. § 41.205.

<u>/ Richard E. Schafer/</u>	)	
RICHARD E. SCHAFER	)	
Administrative Patent Judge	)	
	)	
<u>/ Sally G. Lane/</u>	)	BOARD OF PATENT
SALLY G. LANE	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
	)	
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Patent Interference 105,545 (RES)  
(Technology Center 1600)

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SCHAFER, *Administrative Patent Judge.*

Decision - Motions - Bd.R. 125(a)

- 1 Michigan proposed an amendment narrowing and canceling some of
- 2 its involved claims. Paper 58. The amendment was authorized (Paper 59)
- 3 and Michigan filed the amendment in its involved application (Paper 60).

Based upon the amended claims, the parties jointly move that there is no interference-in-fact between Michigan's amended claims and any of Yeda's claims. Paper 45. The parties' motion for no interference-in-fact is granted.

The parties' claims relate to certain proteins which bind the intracellular domain of the FAS cell receptor. The FAS receptor is a death receptor involved in apoptosis or cellular death related pathways. Binding of these proteins to the intracellular domain of the FAS receptor modulates or mediates the cellular function of a FAS receptor.

#### Findings of Fact

##### The Claimed Subject Matter

F. 1. The parties' claims define their inventions in terms of specific amino acid sequences.

F. 2. Yeda's protein (its Seq. ID No:2) is 256 amino acids in length. Paper 15, p. 7.

F. 3. Michigan's protein (coincidentally also designated Seq. ID No:2) is 208 amino acids in length. Paper 12, p. 5.

F. 4. The two sequences differ in two respects: (1) Yeda's initial 48 amino acid leader sequence is not specifically recited in Michigan's sequence (Ex. 1009, ¶ 23) and (2) the amino acid at position 80 of Yeda's sequence and the corresponding amino acid at position 32 of Michigan's sequence are different (Ex. 1009, ¶ 27).

F. 5. At the corresponding positions Yeda's protein has Valine while Michigan's sequence has Glycine. Ex. 1009, ¶ 28.

F. 6. Yeda's claims do not describe the subject matter of Michigan's claims and vice versa.

1 Obviousness

2 F. 7. There are nearly 5000 potential single residue substitutions that could  
3 be made to Yeda's protein (256 residues x 19 amino acids). Ex. 1009, ¶  
4 43.

5 F. 8. The literature includes many examples illustrating that the  
6 Glycine/Valine substitution effects protein function. Ex. 1009, ¶¶ 57 –  
7 59; Exs. 1004–1008.

8 F. 9. The substitution of Glycine for Valine and vice versa is known to  
9 have a significant potential to adversely affect polypeptide function. Ex.  
10 1009, ¶ 48.

11 F. 10. With respect to intracellular proteins the substitution of  
12 Glycine/Valine substitution is disfavored. Ex. 1009, ¶¶ 52, 53 and 54;  
13 Ex. 1011, pp. 5 and 8.

14 F. 11. One having ordinary skill in the art would have avoided the  
15 Glycine/Valine substitution. Ex. 1009, ¶ 56.

16 F. 12. The effect on the properties of Michigan's and Yeda's proteins by the  
17 substitution of Valine for Glycine and vice versa at position 32 and 80  
18 respectively is highly unpredictable. Ex. 1009, ¶¶ 42; 60-61.

19 F. 13. There is no reasonable expectation of success that the Glycine/Valine  
20 substitution at position 32 of Michigan's protein or at position 80 of  
21 Yeda's protein would result in protein that would modulate or mediate  
22 the cellular function of a FAS receptor. Ex. 1009, ¶ 46.

23 F. 14. Dr. Chinnaiyan, the parties' expert, testifies that he is not aware of  
24 literature or prior art that predicts the impact of the substitution of Valine  
25 and Glycine on the structure of the proteins. Ex. 1009, ¶ 40.

26 F. 15. Dr. Chinnaiyan testifies that he is unaware of any reason to change the  
27 specific amino acid at position 32 of Michigan's protein to Valine or

suggests changing the amino acid at position 80 of Yeda's protein. Ex. 1009, ¶ 41.

### Issue

Have the parties demonstrated that the Glycine/Valine substitution at position 80 of Yeda's protein or position 32 of Michigan's protein would have been unobvious?

### Principals of Law

"An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." 37 C.F.R. § 41.203.

Obviousness of a chemical compound over a similar compound requires some reason to modify the prior art compound. *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007).

### Analysis

Both parties' claims include a reference to specific protein sequences. There are two differences between the respective sequences. The first, and mostly insignificant, is the difference in length of the sequences. Yeda's is 256 amino acids long and Michigan's is 208. Paper 12, p. 5; Paper 15, p. 7. Yeda's protein includes a 48 amino acid leader sequence not included in Michigan's protein. Ex. 1009, ¶ 23. The parties do not argue that the presence or absence of the leader sequence patentably distinguishes the two proteins.

The other difference, which is the focus of the motion, resides in a different amino acid at a corresponding location in each protein. Yeda's protein has Valine at position 80 while Michigan's sequence has Glycine at corresponding position 32. Ex. 1009, ¶ 28.

1 In the parties view, regardless of which sequence is taken as presumed  
2 prior art, it would not have been obvious to substitute one amino acid for the  
3 other at the specific location. Paper 45, p. 7.

4 To support their position, the parties rely on the testimony of Dr.  
5 Chinnaiyan. Dr. Chinnaiyan is qualified as an expert in the subject matter  
6 Ex. 1009, ¶¶ 1-6. Dr. Chinnaiyan testimony is credited.

7 Dr. Chinnaiyan testifies that he is unaware of any reason why one  
8 skilled in the art would choose to change the amino acid at position 80 of  
9 Yeda's protein or position 32 of Michigan's protein. Ex. 1009, ¶ 41. Thus a  
10 person skilled in the art would need to pick for example, the appropriate  
11 amino acid residue to change out of 256 possible choices in Yeda's protein  
12 and then choose Glycine out of 19 other possible amino acid choices. In  
13 other words, a person skilled in the art would have to make the right choice  
14 out of almost 5000 possible modifications. Ex. 1009, ¶ 43.

15 Additionally, the record establishes that Glycine/Valine substitution is  
16 known to effect protein properties and that the substitution has a significant  
17 potential to have an adverse effect. Ex. 1009, ¶¶ 48 and 57-59; Ex. 1004-  
18 1008. The effect of the Glycine/Valine substitution on the properties of the  
19 protein is unpredictable. Ex. 1009, ¶¶ 42 and 60-61. There record also  
20 establishes that a person of ordinary skill in the art would not have a  
21 reasonable expectation that the Glycine/Valine substitution would result in a  
22 protein that would modulate or mediate the cellular function of the FAS  
23 protein. Ex. 1009, ¶ 46. Additionally, with respect to intracellular proteins,  
24 the Glycine/Valine substitution is a disfavored change. Ex. 1009, ¶¶ 52-54.

25 It appears, therefore, that the person having ordinary skill would not  
26 have a reason to modify either of the two proteins by the Glycine/Valine  
27 substitution. Obviousness of a chemical compound requires some reason to



1 modify the prior art compound. *Takeda Chem.*, 492 F.3d at 1356. The  
2 record here establishes by a preponderance of the evidence that one skilled  
3 in the art would have reason not to modify the proteins by substituting  
4 Valine for Glycine and vice versa at the parties' respective positions 80 and  
5 32. The parties have established that this substitution of Valine for Glycine  
6 and vice versa in the parties' proteins would not have been obvious.

7 Accordingly, an interference does not exist between Yeda's claims  
8 and Michigan's amended claims. 37 C.F.R. § 41.203.

9 The parties' joint motion is granted.

10 ORDER

11 It is

12 ORDERED that the parties' joint motion for no interference-in-fact is  
13 granted;

14 FURTHER ORDERED that Yeda's involved claims do not interfere  
15 with Michigan's Claims 61, 72, 73, and 76-78 as shown in Paper 60;

16 FURTHER ORDERED that Michigan's Claims 61, 72, 73, and 76-  
17 78 (Paper 60) do not interfere with Yeda's involved claims; and

18 FURTHER ORDERED that a copy of Michigan's amended claims  
19 (Paper 60) be attached to and is part of this opinion.

20 .  
  
/Richard E. Schafer/  
Administrative Patent Judge

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